

### **REMARKS**

By this reply, claim 158 has been cancelled without prejudice to or disclaimer of the subject matter contained therein; claims 131 and 151 have been amended; and new claim 243 has been added, leaving claims 1-157 and 159-243 pending in the application. No new matter has been added by the amendments.

Reconsideration and allowance are respectfully requested in view of the following remarks.

## **Election of Species Requirement**

Claims 1-130, 132, 134-149, 156, 157 and 159-162 have been withdrawn from consideration. Claims 132-150, 152-157 and 159-162 depend from claim 131. According to M.P.E.P. § 821.04(a), once claim 131 is found to be allowable, withdrawn dependent claims 132, 134-149, 156, 157 and 159-162 should be rejoined.

### First Rejection Under 35 U.S.C. § 102

Claims 131, 151-155 and 158 stand rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,713,954 to Rosenberg et al. ("Rosenberg"). Claim 158 has been cancelled. The rejection is respectfully traversed.

Claim 131, as amended, recites a process for assisting the function of a heart having an outer wall and which is disposed within a patient. The claimed method comprises "importing at least one value of at least one parameter relating to said function of said heart into a controller; using an algorithm to formulate at least one command instruction, based upon said at least one value of said one parameter; and

exporting said at least one command instruction from said controller to assist said heart by effecting changes in volume of a drive fluid within a single continuous cavity of variable volume extending circumferentially around said outer wall of said heart" (emphasis added). Support for the amendments to claim 131 can be found, for example, at page 56, lines 17-31, and in the paragraph bridging pages 66 to 67, of the present specification.

Claim 131 is directed to a process for assisting the function of the heart within a patient. The heart has an outer wall. The heart is assisted by effecting changes in volume of a drive fluid within a single continuous cavity of variable volume extending circumferentially around the outer wall of the heart. For example, in the exemplary embodiment shown in Figure 2B, there is a single continuous cavity of variable volume between the liner 114 and shell wall 112. The single continuous cavity can extend circumferentially around the outer wall of the heart. As further recited in claim 131, the process comprises exporting at least one command instruction from a controller to assist the heart by effecting changes in volume of the drive fluid within the single continuous cavity of variable volume.

Rosenberg fails to disclose each and every feature of the process recited in claim 131. Rosenberg discloses an extra cardiac ventricular assist device. The device shown in Figure 2 of Rosenberg, for example, includes an artificial myocardium 11 in the form of a cuff connected to an energy converter 19 and a hydraulic reservoir 21. As shown in Figure 3B of Rosenberg, the cuff 11 includes numerous cylindrical tubes connected along their axially extending walls and that together extend completely around the cuff. Each of the multiple tubes of the cuff 11 includes a cavity; thus, the cuff includes numerous separate cavities into which

hydraulic fluid is introduced. The cuff 11 does <u>not</u> include a single continuous cavity of variable volume extending circumferentially around the outer wall of a heart, as recited in claim 131. Accordingly, for at least this reason, Rosenberg does not anticipate the process of claim 131.

Claims 133 and 151-155, which depend from claim 131, are also patentable over Rosenberg. Therefore, withdrawal of the rejection is respectfully requested.

#### Second Rejection Under 35 U.S.C. § 102

Claims 131, 133, 150-155 and 158 stand rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,626,821 to Kung et al. ("Kung"). The rejection is respectfully traversed.

Applicants respectfully submit that Kung also fails to disclose each and every feature of the process recited in claim 131. Kung discloses a flow-balanced cardiac wrap for enclosing a ventricular region of the heart. The embodiment of the cardiac wrap 110 shown, for example, in Figure 1 of Kung, includes numerous inflation elements 112 arranged in parallel longitudinally. Each of the individual inflation elements 112 defines a separate cavity of variable volume, which is inflatable to apply pressure to the heart 100 on which the wrap 112 is fitted. Kung depicts other embodiments of the wrap in Figures 7-13, 19 and 23-25, for example. Each of these other embodiments also includes multiple inflation elements, each defining a separate cavity, such that each wrap includes multiple cavities. Kung does not disclose a wrap including a single continuous cavity of variable volume extending circumferentially around the wall of a heart, as recited in claim 131. Accordingly, Kung does not anticipate the process recited in claim 131.

Claims 133 and 151-155 depend from claim 131 and thus are also patentable over Kung. Therefore, withdrawal of the rejection is respectfully requested.

### **New Claims**

New independent claim 243 is directed to a process for assisting the function of a heart including a left ventricle, a right ventricle and an outer wall, where the heart is disposed within a patient. The process comprises, *inter alia*, "exporting the at least one command instruction from the controller to assist the heart by effecting changes in volume of a drive fluid within a first cavity of variable volume corresponding to the left ventricle and a separate second cavity of variable volume corresponding to the right ventricle, the first and second cavities together extending circumferentially completely around the outer wall" (emphasis added). Support for claim 243 can be found at page 70, lines 3-11, of the present specification. Claim 243 is also patentable.

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# **Conclusion**

For the foregoing reasons, allowance of the application is respectfully requested. Should the Examiner have any questions concerning this response, to expedite prosecution, the Examiner is respectfully requested to contact the undersigned at the number given below.

Respectfully submitted,

**BUCHANAN INGERSOLL PC** 

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